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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/365,241      07/30/99      BRODIN      T      003300-581

021839      HM12/0619  
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EXAMINER

WESSENDORF, T	
ART UNIT	PAPER NUMBER


1627      (6)  
DATE MAILED:      06/19/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No. <b>09/365,241</b>	Applicant(s) <b>Brodin et al</b>
Examiner <b>T. Wessendorf</b>	Art Unit <b>1627</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1)  Responsive to communication(s) filed on 4/6/01
- 2a)  This action is FINAL.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4)  Claim(s) 1-4, 6-7, 9-10, 17-64 is/are pending in the application.
- 4a) Of the above, claim(s) 58-60 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-4, 6, 7, 9, 10, 17-57, and 61-64 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a)  All b)  Some\* c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)                      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_                      20)  Other: \_\_\_\_\_

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 61-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recited "any other homogeneous binding structure" is not supported in the as-filed specification. Applicants are requested to specifically point out where in the specification said recitation can be found. Also, e.g., claim 61 recitation of "combination of subtractive tissue selections"; claim 62 "both positive and negative tissue selections, with different types of libraries" or the method step of claim 64.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4, 6-7, 9-10, 17-57, 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

A). It is argued that the amendments to claim 1 including step(e) has obviated the indefinite phrase "by means of a first library of binding structure(s)." Claim 1 does not contain a step (e). Assuming the last step is step (e) however, this does not clarify the "means" step especially the step merely repeats what is in the preamble. The means by which isolation is achieved is not clear from the claimed context. It is not clear whether isolating the desired binding structure against a target structure relates to isolating the binding structures from the target structure or isolating both.

Applicants argue that the "other identifying information" is disclosed at page 7, lines 9-14. A review of said page 7 does not disclose any other identifying information of the gene and merely contains statement as indefinite as in the claims. Applicants submit one of skill in the art would know that in the context of the present invention said phrase refers to information used to

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identify individual components of the libraries. However, in the context of the present invention, it would be unclear especially since all of the components in the method are not clearly defined or positively identified as the argued, chemical tags.

It is argued that claim 1 has been amended to clearly distinguish between first and second library. The arbitrary designation of these relative terms are still not clearly set forth. For example, is the second library, another newly created library or simply compounds isolated from the first (starting library)? Also, while applicants have amended the base claim by deleting the term "characterized", however the dependent claims e.g., 17-21 have not been correspondingly amended. Applicants are requested to check for the other dependent claims to make sure that they have antecedent basis of support from the base claim or the preceding claims.

Since applicants have not responded to the rejection of claim 1 as being indefinite in the recitation of acquiring a binding structure(s) which appears that it is the compound structure (e.g., tertiary or secondary) that is obtained rather than conventionally a compound e.g., antibodies or antigen or ligand or receptor, it is believed that applicants are acquiescing therewith. Also, the rejection with respect to the

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whole process steps being confusing. How can a first library be reacted with a target structure in vivo and in situ, how is such reaction determine and how is the target structure displayed in vivo and in situ? How can the target be displayed when it is the binding structure that is linked to the gene?

It is argued that with the deletion of the rejected terms in claim 4, the rejection has been obviated. However, homogeneous still appears in the claims and together with the terms any other renders it more indefinite, especially in the absence of positive support as to the any other homogeneous binding structure.

It is argued that a skilled artisan would know what is meant by "previously uncharacterized, unpurified and unknown molecules" but fail to provide any evidence from the art and merely presents a list such as antibodies, protein, inter alia. Thus, it is not clear as to the what other molecules are included in said undefined boundaries of the claim. Attention has been directed to the Tse of record. However, this claim do not contain the argued limitation of antibodies and antigens.

It is argued that the rejection in claim 7 has been obviate by replacing expressed with displayed. Display is not also in the base claim since this term has been canceled from the base claim.

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It is argued that in claim 22 the phrase portion or set of antigens has been replaced with portion or a set thereof. This does not obviate the rejection, as the metes and bounds of the portion or of the set is indefinite.

With regards to claim 23, changing the dependency does not obviate this rejection, especially in view of the arguments that the protein-type structure is not the pure form of one structure but a combination of several such structures. Also, the displayed is not in the base claim.

It is argued that with the newly added limitation in claim 24 of a specific embodiment of a method of obtaining tissue by histological method obviates this rejection. Histological method is clearly different from the base claim method of obtaining e.g., an antibody.

Claims 30 and 32, for example, are unclear, within the claimed context, as to the passive or active secretions of e.g., body fluids.

Claim 39 is unclear as to the basis or standard of preselection of a library.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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a person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-7, 9-10, 17-50, 54 and 61-64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of Tse et al (WO 94/26787) or Williams et al(Immunotechnology) or under 102(e) over either Rouslahti et al (5,622,699) or O'Mahony (6,117,632) for reasons advanced in the last Office action.

It is argued that Tse fails to teach or suggest the direct elution of phage particles. None of the claims recite for this argued phage particles or its elution. It is further argued that the claims do not recite copurification as done by Tse. The



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claimed comprising does not preclude any other steps from those claimed therein. Likewise the argued displayed target structure location is not a limitation appearing in the claims. Therefore, the specific steps of Tse reciting specific components anticipates or renders obvious the broad claimed invention.

Applicants did not appear to have any difficulty apprehending the abstract of the Williams reference since it is argued that the abstract of the meeting discloses FV regions from the libraries of autoimmune patients selected by in vivo blood circulation panning and that the blood circulation panning only yields binders to structures accessible from the vasculature and therefore distinguishable. Nevertheless, argue that the present invention relates to the displayed target structure located in a cell membrane etc. As stated above this argued limitation does not appear in the claims.

The same arguments above are applied to Rouslahti since applicants merely presented the same arguments.

It is argued that O'Mahony does not involve transport across tissue and cell barriers. See the response under Tse above as not being commensurate in scope with the claims.

Claims 56-57 are free of prior art.

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This application contains claims 58-60 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CAR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

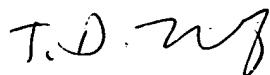
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Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 2:30.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tdw  
6/15/01

  
T.D. WESSENDORF  
PRIMARY EXAMINER